REMARKS

I. Office Action Summary

Claims 64-81 are pending. Claim 77 is the only independent claim. In the Office Action dated June 28, 2007, all of the pending claims were rejected as obvious over the combination of Chester (WO 82/00413 A1) in view of Smith et al. (U.S. 5,0131,613) and further in view of Blake et al. (U.S. 3,634,924).

II. Interview Summary

A telephone interview was held on September 24, 2007. The undersigned thanks Examiner Chapman for the courtesy extended in that call. A proposed amended Claim 77 and claim 80 was discussed and the prior art of record was noted. The Examiner indicated she would consider amendments along the lines of those proposed, however no specific agreement was reached.

III. Objections to the Claims

The Examiner indicated that dependent claim 81 was a substantial duplicate of independent claim 77. Applicant respectfully disagrees. Claim 81 recites that at least a portion of the catheter recited in claim 77 is constructed of a compliant material. Claim 77 does not recite that at least a portion of the catheter is constructed of a compliant material. Accordingly, Applicant submits that these claims differ in scope.

With reference to claim 73, Applicant has amended this claim to correct the spelling error noted by the Examiner.

IV. Claim Rejection Under 35 U.S.C. § 112, first paragraph

Claim 79 was rejected as allegedly lacking support the term "tether" from the specification. Applicant respectfully submits that a tether is commonly understood to refer to a cable, cord or line that connects two things together, and that the disclosure in the specification of a wire anchoring an end of a catheter to a point along the catheter shaft is a disclosure of a type of tether. Accordingly, Applicant submits that there is sufficient support under 35 U.S.C. §112 , paragraph 1 for the term tether in claim 79 and requests that this rejection be withdrawn.

V. Claim Rejection Under 35 U.S.C. § 103(a)

A. Rejection of Claims 77-78, 64-74, 76 and 81 Over the Combination of Chester, Smith and Blake

CLAIM 77

Independent claim 77 relates to a method of forming a catheter for nebulizing a liquid with a gas where the method includes the steps of:

> **providing a multilumen extruded polymer tubing;**
> heating a portion of the tubing to a transition temperature of said tubing;
> **forming a j-shaped distal section in the multilumen extruded polymer tubing at a distal end of the catheter, wherein the multilumen extruded polymer tubing in the j-shaped distal section maintains a shape at rest that curves away from a longitudinal axis of the catheter; and**
> forming a plurality of orifices at the j-shaped distal section, said plurality of orifices being sized to nebulize a liquid delivered through one of said lumens to form an aerosol with a gas delivered through another of said lumens.

The Chester reference lacks any teaching of at least the above bolded elements of claim 77. Chester discloses medical tubing with embedded radiopaque material in its walls. The Office Action appears to mistake the integrally formed strips of radiopaque material (items 16,18,24,26, 28 and 30 in the Figures) in the wall 14 of the tubing for lumens. The section of Chester cited in the Office Action, p. 3, lines 30-33, continues on in lines 33-36 to state that the radiopaque material is coextruded with the tubing material. Thus, there is only a single lumen in Chester with two or more strips of radiopaque material embedded in the wall of the single lumen. Applicant notes that the multilumen tubing recited in the method of claim 77 is used to form a plurality of orifices, where separate lumens have respective orifices. Accordingly, Applicant does not believe the statement in the Office Action regarding multilumen tubing lacking patentable weight is supportable.

Additionally, Chester lacks any teaching or suggestion of forming a j-shape distal section. Applicant notes that neither the cited section of Chester, p. 8, lines 16-21, nor any other part of the text, mention any overall shape or form for the tube. The figures in Chester also lack any teaching or suggestion of forming a j-shape at a distal end.

Smith also fails to teach or suggest the above bolded elements of claim 77. Rather than teaching multilumen extruded polymer tubing, Smith discloses a catheter 2 that is removably placed inside an endotracheal tube 4. Applicant notes that a lumen 40 may be attached on the outside of, and partway down the length of, the endotracheal tube and connected with a balloon 12 on the outside of the endotracheal tube (See FIG. 1). This does not appear to be any type of multilumen extruded polymer tubing and the specification does not teach or suggest that type of construction. Thus, the catheter of Smith is a single hollow tube and does not disclose a multilumen extruded polymer tube as claimed.

Applicant also notes that the separate endotracheal tube 4 in Smith is generally curved along its entire length. The bendable, single-lumen, catheter 2 inserted therein also follows this curve. No j-shape is evident at the distal end of the tube or catheter. Instead, Smith shows a pinched "hour-glass" shaped neck near its distal end 8 (see embodiments of FIG. 2 and FIG. 4 in Smith). Accordingly, Smith also lacks at least the j-shaped distal section where a multilumen extruded polymer tubing curves away from a longitudinal axis of the catheter at a distal end of the catheter.

The third reference cited by the Examiner, Blake, discloses a method of making a balloon catheter with improved support for balloon windings. Although Blake discloses a multi-lumen catheter, Blake discloses a method that "is of particular advantage in making flow-directed catheters having a soft and limp tube." (Col. 1, lines 42-45). No disclosure of forming a catheter with a j-shaped distal end is found in Blake. Additionally, Blake fails to disclose a plurality of orifices in the distal end sized to nebulize a liquid delivered through one orifice with a gas delivered though another orifice as claimed. Blake discusses the injection of sampling or diagnostic agents, measuring pressure and body fluid sampling (Col. 2, lines 65-69) and provides an example of inserting a catheter in to a vein (Col. 2, line 72 – Col. 4, line 18) where introduction of a gas for nebulization would be untenable.

Applicant has amended claim 77 to emphasize that the method includes forming a j-shaped distal end such that the j-shaped distal section at the distal end of the catheter maintains a shape at rest that curves away from a longitudinal axis of the catheter. Applicant submits that support for this language is found throughout the

specification, for example with respect to embodiments shown in FIGS. 28, 29 and 30. This is in contrast to any of the cited references which disclose straight or limp catheters that are not formed to maintain a j-shape. Because of the lack of disclosure or suggestion of all the elements of claim 77 in Chester, Smith, and Blake alone or in combination, Applicant submits that amended claim 77 is allowable over the art of record. Claims 64-76 and 78-81 are dependent claims, therefore their allowability directly follows from the allowability of independent claim 77. Reconsideration and allowance is respectfully requested.

B. Rejection of Claims 64-65, 75 and 79-80 Over the Combination of Chester, Smith and Blake

Applicant respectfully disagrees with the Examiner's rejection and submits that, in addition to the patentably distinct features recited in these claims, dependent claims 64-65, 75 and 78-79 are allowable for at least the same reasons as provided for independent claim 77.

As noted above, Blake fails to make up for the deficiencies of Chester and Smith. The Examiner previously noted (Office Action dated April 6, 2006, p.6) that Blake lacks any teaching or suggestion of a j-shaped distal end. Applicant agrees that Blake lacks at least this feature of claim 77. Additionally, Applicant notes that the catheter disclosed in Blake is a balloon catheter having "a soft and limp tube" (col. 1, line 45). As recited in Blake, "the catheter tube has a balloon inflation lumen 53 and a through flow lumen 54, the tube being flexible to the extent of being completely limp" (col. 3, lines 5-7). The disclosure of Blake goes on to further emphasize the straight-ended catheter through its discussion of the balloon that is inflated to prevent the tip of the catheter from damaging a heart or artery wall. Specifically, the disclosure recites:

> when the balloon 60 is inflated, the annular bulge 65 prevents point contact of the tip of the catheter tube with the heart or artery wall. The presence of the balloon around the tip of the catheter alters the catheter system from one with a point force to one with forces dispersed over a surface. (col. 4, lines 10-12)

Thus, not only does Blake fail to teach or suggest a j-shaped distal section as claimed, it also teaches away from such a feature through its discussion of the completely limp tube and the balloon to disperse pressure that might otherwise be focused at the point

of the catheter. Accordingly, there is no motivation to combine Blake with a catheter having a j-shaped distal section either.

Although a wire is mentioned in Blake, the disclosed wire is "inserted temporarily" into a lumen while a tip section is being formed and then removed (Blake, Col. 2, lines 38-45) and not embedded in the tube to fabricate a radiopaque stripe, as recited in dependent claim 75, or related to steps of attaching a tether to a shaft of the catheter and an end of a j-shaped distal section as recited in claims 79-80. Claim 80 has been amended to clarify how the tether may be a wire attached to the end and the shaft of the catheter and Applicant submits that this amendment is fully supported by the specification.

Applicants submit that claims 64-65, 75 and 79-80 are allowable over the cited references.

III. Conclusion

With the above remarks and amendments, Applicant submits that claims 64-81 are in condition for allowance. Reconsideration and allowance is respectfully requested.

Respectfully submitted,

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